

REMARKS

The Office Action of July 9, 2009 presents the examination of claims 1, 3-8, 36 and 37. These claims remain pending and are not amended further.

Rejection over Bijli (2003)

Claims 1, 3-8, 36 and 37 remain rejected under 35 USC § 102(a) as anticipated by Bijli et al. (2003). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Attached hereto is a "Katz" Declaration establishing that only a subset of the authors of the Bijli (2003) publication could properly be named as co-inventors of the subject matter of the present application, since one of the co-authors, S. N. Gaur merely provided serum samples for analysis at the request of one of the co-inventors, B. P. Singh. Thus, S. N. Gaur is listed as a co-author of the publication, but did not provide any "mental contribution" to the making of the present invention and so is not listed as a co-inventor of the present invention.

Accordingly, the Bijli et al. (2003) reference is not work "by another" and also was not published more than one year prior to the filing date of the present application. Thus, the instant rejection should be withdrawn.

Rejection over Bijli (2002)

Claims 1, 3-8 and 36-37 remain rejected under 35 USC § 102(b) as anticipated by Bijli et al. (2002). This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Applicants have repeatedly described the differences between the presently claimed protein and that disclosed in Bijli et al. (2002). Applicants reiterate that the protein disclosed in the cited reference has an amino-terminus that is blocked. For whatever reason that this has occurred, the amino-terminal sequence of such "isolated" protein as disclosed by Verma (2000) cannot be determined by Edman degradation. The Examiner apparently urges that the protein of Bijli (2002) are the same as that in Verma (2000) and in the present invention, because they are obtained from the same grass and have the same molecular weight. If this is the Examiner's

basis for alleging anticipation by Bijli (2002), then the proteins disclosed in this reference must also be considered to have a blocked amino-terminus. On the other hand, the protein of the instant invention is readily sequenced by an Edman process, which requires that the protein have a "free" amino terminus. These facts are clearly established by the Declaration of Naveen Arora (filed with Applicants' paper of February 6, 2006), and they establish a plain difference in the chemical nature of the protein disclosed in the cited reference and the protein of the instant invention.

Since there is substantial evidence in the record to establish a chemical difference between the protein of the present invention and that of the Bijli (2002) reference, the anticipation rejection over Bijli (2002) should be withdrawn.

Second, the Examiner is asserting inherency of the various biochemical activities recited in the claims. That is, the present claims recite that the protein of the invention has biological activity of "inhibits proteolytic cleavage of protective antigen (PA) of *Bacillus anthracis* in a dose dependent manner", and the Examiner asserts that the protein of Bijli (2002) inherently has this same biological activity, because:

"Products of identical chemical composition can not have mutually exclusive properties. [A] chemical composition and its properties are inseparable."
Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

This statement by the Examiner betrays a complete lack of understanding of protein biochemistry on the part of the Examiner. Even if composition of the protein of the present invention is "identical" (and this is not conceded by Applicant in view of the nature of 1-D PAGE that it only separates proteins by molecular weight, and at least the amino-terminal amino acid in the claimed protein is free), the 3-dimensional shape of the protein can be different, depending on how the protein is treated.

In particular, it is well known in the art that the SDS-PAGE separation process used in Bijli (2002) denatures, i.e. unfolds, the 3-dimensional structure of a protein, since a detergent (SDS) and a disulfide reductant (B-mercaptoethanol) are added to the proteins for this purpose during the preparation of the sample for the analysis. The sample is also boiled to assure unfolding of proteins in the sample.

It is further well-known in the art that biological activities of proteins generally requires that they are in their "native" (i.e. normally folded) form.

Thus, one of ordinary skill in the art reading Bijli (2002) would understand that, contrary to the Examiner's assertion of "inherent" activity, the protein "isolated" by SDS-PAGE would probably **not** have the biological activity of "inhibits proteolytic cleavage of protective antigen (PA) of *Bacillus anthracis* in a dose dependent manner".

Since the record of the present application contains evidence of at least two differences between the presently claimed protein and that disclosed by Bijli (2002), the instant rejection of claims 1, 3-8 and 36-37 under 35 USC § 102(b) as anticipated by Bijli et al. (2002) should be withdrawn.


Applicants submit that the presently-claimed invention is novel and unobvious over the prior art of record. The favorable actions of withdrawal of the standing rejections and allowance of the claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D., Reg. No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated: December 9, 2009

Respectfully submitted,

By 
Mark J. Nuell
Registration No. 36,623
BIRCH, STEWART, KOLASCH & BIRCH, LLP
12770 High Bluff Drive, Suite 260
San Diego, California 92130
(858) 792-8855
Attorney for Applicant

Attachment:
"In re Katz" DECLARATION